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Daisuke Awakura

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HOLTZ, HOLTZ, GOODMAN & CHICK PC
220 Fifth Avenue
16TH Floor
NEW YORK, NY 10001-7708

EXAMINER

SZNAIDMAN, MARCOS L

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

This office action is in response to applicant's request for continued examination filed on July 2, 2010.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission and amendments filed on January 12, 2010, have been entered.

Status of Claims

Amendment of claims 11, 16, 31 and 35 is acknowledged.

Claims 11-35 are currently pending and are the subject of this office action.

Claims 14, 19 and 26 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 16, 2009.

Claims 11-13, 15-18, 20-25 and 27-35 are presently under examination.

The following species, elected by Applicant in the reply filed on January 16, 2009, are under examination: potassium phosphite as the elected species for Compound A.

Priority

The present application is a 371 of PCT/JP03/15543 filed on 12/04/2003, and claims priority to foreign application: JAPAN 2002-352697 filed on 12/04/2002.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103 (New Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-13, 15-18, 20-25, 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirgozliev et. al. (European Journal of Plan Pathology (2002) 108:469-478, cited in prior office action) in view of Staub et. al. (US 4,849,219, cited in prior office action) in view of.

Claims 11-13, 15, and 29-34 recite a method for inhibiting or reducing mycotoxin contamination (wherein the mycotoxin is deoxynivalenol (DON), see claims 30 and 32) in a cereal (wherein the cereal is wheat, see claims 29 and 33-34) comprising a step of applying potassium phosphite (species elected for compound effective for inhibiting production of mycotoxin) in an amount sufficient for inhibiting mycotoxin production from plant pathogenic fungi in a cereal up to an amount of 0.56% wt as converted into P₂O₅.

For claims 11-13, 15, 29-34, Pirgozilev teaches a method of inhibiting or reducing the amount of the mycotoxin deoxynivalenol (DON) in wheat comprising the administration of a fungicide like metconazole or azoxystrobin (see for example title and abstract). Pirgozilev further teaches different amounts of fungicide to be applied (see Table 2 on page 471) at a rate of 200 l ha⁻¹. Pirgozilev clearly teaches that *Fusarium* is a destructive fungal disease of wheat and other small grain cereals. Then Pirgozilev teaches the strains that are most associated with the disease (see Introduction, left column). Then Pirgozilev further teaches that DON is one of the mycotoxins produced by several *Fusarium* species (see page 469, right column, second paragraph).

Pirgozilev does not teach reducing DON with potassium phosphite. However, Staub teaches a fungicidal composition comprising potassium phosphite (e.g. monopotassium phosphite and dipotassium phosphite, see column 4, lines 1 and 3) useful for the treatment of *Fusarium* fungi (see column 5, line 6) in crops like wheat (see column 5, line 24).

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such “picking and choosing” within several variables does not necessarily give rise to anticipation. *Corning Glass Works v. Sumitomo Elec.*, 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables (potassium phosphate as the antifungal, *Fusarium* as the fungi, and wheat as the cereal), anticipation cannot be found.

That being said, however, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007)(quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” *Id.* at 1742.

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Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients (potassium phosphate as the antifungal, *Fusarium* as the fungi and wheat as the cereal) from within a prior art disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”.

Staub further teaches that advantageous rates of application are normally from 100 g to 2, 000 g a.i./ha (see column 6, lines 13-15).

Since Pirgozilev teaches reducing DON contamination comprising the administration of a fungicide that controls certain *Fusarium* species and since Straub teaches that potassium phosphate is a fungicide that controls certain *Fusarium* species, at the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to substitute one functional equivalence (a fungicide that controls certain *Fusarium* species) for another (potassium phosphate) with an expectation of success, since the prior art establishes that both function in similar manner.

Further, neither Pirgozilev nor Straub teach the administration of potassium phosphate up to an amount of 0.56% (Kg/l) as converted into P₂O₅ (this is the equivalent of 560 g/ha at an application rate of 100 L per 10 a, see page 8, line 10 of the specification). However, Staub further teaches that advantageous rates of application are normally from 100 g/ha to 2, 000 g/ha , preferably 100 g/ha to 600 g/ha (see column 6, lines 13-15). These amounts overlap with the amounts of the instant claims. MPEP 2144.05 states: In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *In re*

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Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990). Thus resulting in the practice of claims 11-13, 15, 29-34 with a reasonable expectation of success.

Claim 35 further limits claim 11 wherein the amount of deoxynivalenol is reduced to 1.1 ppm or less.

For claim 35, Pirgozliev further teaches: that the FDA recommends that DON concentrations should not exceed 1000 micrograms/kg (i.e. 1 ppm) in finished wheat products (see page 470, left column, middle of the page). Pirgozliev also teaches that depending on the amount and type of fungicide the amount of DON can be reduced to undetectable amounts (less than 1.1 ppm, see Table 5, second and third line of experiment 1).

Based on this, and since it is within the capability of the ordinary skilled in the art to modify amounts for a specific treatment and adjust those particular amounts to observed effectiveness, the skilled artisan would have been further motivated to determine the amount of potassium phosphite required in order to reduce the amount of DON below the level required by the FDA, thus resulting in the practice of claim 35 with a reasonable expectation of success.

Claims 16-18, 20-25 and 27-28 further limit claim 11, wherein the composition further comprises an effective amount of at least one fungicidal active ingredient for agri-horticulture (azoxystrobin in claims 21-25 and 27-28).

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For claims 16-18, 20-25 and 27-28 Pirgozliev further teaches a method for reducing the amount of the mycotoxin deoxynivalenol (DON) that is released by *Fusarium*, comprising the administration of azoxystrobin (see abstract).

At the time of the invention it would have been *prima facie* obvious for a person of ordinary skill in the art to inhibit or decrease the amount of deoxynivalenol contamination in wheat, combining two compositions (potassium phosphite and azoxystrobin) each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (see MPEP 2144.06). *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). All this would result in the practice of claims 16-18, 20-25 and 27-28 with a reasonable expectation of success.

Response to Applicant's arguments related to the above rejection

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that:

The present inventors were the first to discover that the compounds recited in Applicant's claims have the effect of reducing an amount of a mycotoxin, such as DON, produced in a cereal, even when *Fusarium* head blight (FHB, a crop disease) is generated in a plant body or even when *Fusarium* fungi remains the same.

Examiner's response:

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Apparently, Applicant has discovered a new property or advantage (i.e. reducing an amount of DON, produced in a cereal, even when *Fusarium* head blight is generated in a plant body or even when *Fusarium* fungi remains the same) of the method made obvious by the prior art (decreasing the amount of DON with Potassium Phosphite). MPEP 2145 II states: "The fact that Applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art, cannot be the basis for patentability when the differences would otherwise be obvious" *Ex parte Obiaya*, 227 USPQ 58, 60.

Applicant argues that:

Staub et. al. concern microbicides. Staub et. al. is directed to a fungicidal composition. In the paragraph bridging columns 3 and 4, Staub et al. describe over twenty-five different fungicides. In column 5, Staub et. al. list almost seventy different species of plants and fifteen different fungi.

In contrast to Staub et al., the purpose of the presently claimed invention is to inhibit the production of a mycotoxin by a compound as recited in applicants' claims, even if *Fusarium* head blight exists in a plant. There is no specific reason to select a compound as recited in applicant's claims, such as potassium phosphite, from the fungicides disclosed in Staub et al. to inhibit mycotoxin contamination in crops.

Examiner's response:

As mentioned in the above 103 rejection: it would have been obvious to select various combinations of various disclosed ingredients (potassium phosphate as the

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antifungal, Fusarium as the fungi and wheat as the cereal) from within a prior art disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”. And since Pirgozilev teaches a method of decreasing DON comprising the administration of a fungicide like metconazole or azoxystrobin, known to be effective against different species of Fusarium, at the time of the invention it would have been obvious to substitute one functional equivalence (a fungicide that controls different species of fusarium like metconazole or azoxystrobin) for another (potassium phosphate) with an expectation of success, since the prior art establishes that both function in similar manner.

Applicant argues that:

Pirgozliev et al. concern only a study wherein metconazole and azoystrobin, fungicides used for the control of Fusarium head blight, resulted in elevated concentration of deoxynivalenol mycotoxin.

Pirgozliev et al. do not teach or suggest any of the compounds effective for inhibiting production of a mycotoxin by plant pathogenic fungi of cereals which are recited in applicants' claims.

Pirgozliev et al. disclose the effects of prevention of FHB and reduction of the concentration of a mycotoxin by specific chemicals, such as azoxystrobin or metconazole. But there is no description or suggestion for prevention of FHB or inhibiting a mycotoxin by a compound as recited in applicants' present claims.

Examiner's response:

If Pirgozliev would have taught a compound like potassium phosphate for inhibiting production of mycotoxin by plant pathogenic fungi of cereals, it would probably have been a 102 rejection instead of a 103. Pirgozliev clearly teaches that the source of DON is the presence of certain strains of Fusarium which are present in wheat (see title and abstract).

Applicant argues that:

The characteristic feature of the presently claimed invention resides in applying a compound as recited in applicants' claims that does not necessarily completely kill the fungi, but prevent mycotoxin production°. Such result is submitted to be remarkably surprising and indeed could not be expected from using conventional fungicides.

Examiner's response:

Pirgozliev does never claim that that the fungus has to be completely killed in order to prevent mycotoxin production. Indeed from the results of tables 3, 4 and 5 the skill in the art will conclude that although related, it is not absolutely necessary to kill the fungus completely in order to prevent DON production.

In summary: apparently applicant has discovered that under certain conditions (i.e. an amount of potassium phosphite less than 0.56 %) the amount of DON is decreased below 1 ppm without necessarily having to kill fusarium fungi. However, the same compound in a similar or same amount is described or made obvious by the prior art in order to treat the same problem, as such, whatever mechanism or new property

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Applicant has discovered for this process, it would have naturally flow from the teachings of the prior art, since the same compound (potassium Phosphate) is administered in the same or similar amounts (100 g/ha to 2, 000 g/ha) to the same crops (wheat) that are contaminated by the same fungi (fusarium). In other words, products of identical or similar composition cannot exert mutually exclusive properties when administered under the same or similar circumstances.

MPEP 2145 II states: "The fact that Applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art, cannot be the basis for patentability when the differences would otherwise be obvious" *Ex parte Obiaya*, 227 USPQ 58, 60.

Applicant argues that:

As discussed above, the presently claimed invention satisfies a long felt need in the art.

Applicants have informed the undersigned that corresponding applications in Europe, Australia and New Zealand have been allowed.

Examiner's response:

None of the above applications have been presented to the Examiner. Applicant is encouraged to do so.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
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September 26, 2010.